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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/378,759	08/23/1999	GARY M. FOX	06843.0027-0	9481

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EXAMINER	
BRANNOCK, MICHAEL T	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 11/18/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/378,759	Fox et al.
Examiner	**Art Unit**
First Last	1234

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Sep 3, 2002*.

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *28, 29, 31, and 36-56* is/are pending in the application.

4a) Of the above, claim(s) *28, 29, 31, 36, and 37* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *38-56* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☒ The drawing(s) filed on *Aug 23, 2002* is/are a) ☐ accepted or b) ☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Status of Application: Claims and Amendments

1. Applicant is notified that the amendments put forth in Paper 18, 9/9/02, have been entered in full.

2. Claims 28, 29, 31, 36-46 and new claims 47-56 are pending.

Claim 28 and has been amended to excluded the elected species of SEQ ID NO: 11, therefore claims 28, 29, 31, 36 and 37 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Drawings

3. The drawings are objected to as set forth the Notice of Draftsperson's Patent Drawing Review Form PTO-948, which was attached to Paper 12, 9/25/01. No proposed drawing correction or corrected drawings have been received. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Maintained and New Rejections:

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 43, 46, 51 and 56 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims require a pharmaceutical composition yet the specification does provide sufficient guidance as to what the antibody is therapeutically effective for; and neither can such a use be reasonably inferred from the prior art, as set forth previously. Applicant argues that due to the recognized relationship between Hek5 and gastric cancer, the artisan would recognize that this correlation suggests that the antibodies may be used, e.g. to specifically target anticancer agents to cancer cells. This argument has been fully considered but not deemed persuasive. There is no mention of such a use in the instant specification and there are no references of record that would lead the artisan to this conclusion.

Applicant argues that the claims have been amended to remove the phrase "therapeutically effective amount", thus rendering the rejection moot. This argument has been fully considered but not deemed persuasive. The term "pharmaceutical composition" implicitly

requires that the composition be used for some form of treatment or therapy. As put forth above, the specification has not provided sufficient guidance as to how to make and use a pharmaceutical composition.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claim 47 and 52 rejected under 35 U.S.C. 102(b) as being anticipated by Pasquale EB, Cell Regulation 2(7)523-534, 1991, see Information Disclosure Statement of Paper number 2, as applied to claims 38 and 39 in item 10 of Paper 15, 4/4/02.

Pasquale disclose polyclonal antibodies that bind Cek5 (see the Abstract). The Cek5 polypeptide is 95% identical to the instant SEQ ID NO: 11, as set forth previously. Further, as Cek5 and the instant Hek5 contain more portions in common with each other than portions that are different, the Pasquale antibodies were raised against a portion of Hek5. Also, absent evidence to the contrary, the polyclonal antibodies disclosed by Pasquale are expected to bind to the polypeptide of SEQ ID NO: 11. Applicant argues Pasquale fail to teach every element of the claim. This argument has been fully considered but not deemed persuasive. Pasquale teach

every element of certain embodiments of generic claims 47 and 52 because the claims only require that the antibodies be raised against a portion of Hek5, as discussed above.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 38-42, 44, 45, 48-50, 53-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pasquale EB, Cell Regulation 2(7)523-534, 1991, as applied to claims 47 and 52 above, in view of U.S. Patent No: 4816567.

Claims 38-42, 44, 45, 48-50, 53-55 require the antibody of claims 47 and 52 yet claims 38-42, 44, 45, 48-50, 53-55 also require that the antibody be a monoclonal, chimeric, or CDR grafted antibody. 4816567 teaches that in the art of antibody production, monoclonal antibodies are generally preferred to polyclonal antibodies (col 2, line 17), while CDR grafted and otherwise chimeric antibodies are more preferred, see col 2, lines 40-65 and cols 15 D.6 and D.7).

Therefore, it would be obvious to one of ordinary skill in the art at the time the invention was made, with reasonable expectation of success, to make a monoclonal, chimeric, or CDR grafted antibodies according to U.S. Patent No: 4816567 when practicing the invention of Pasquale EB. The motivation to do so is provided by U.S. Patent No: 4816567 wherein in is

indicated that in the art of antibody production, monoclonal antibodies are generally preferred to polyclonal antibodies (col 2, line 17), while CDR grafted and otherwise chimeric antibodies are more preferred, see col 2, lines 40-65 and cols 15 D.6 and D.7).

Applicant arguments regarding Pasquale have been addressed above.

10. Claims 42, 44, 45, 47-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iwase et al., Biochem. Biophys. Res. Comm. 194(2)698-705, 1993 in view of U.S. Patent No: 4816567, as set forth previously regarding claims 38-42, 44 and 45.

Applicant asserts that the polypeptide taught by Iwase et al. (H1) is similar to positions 624-970 of the instant SEQ ID NO: 11 with the exception of 3 amino acid differences. Thus H1 and the instant SEQ ID NO: 11 have large portions in common. Iwase et al., teach that the polypeptide (H1) is dramatically up regulated in human gastric cancers and the dysregulation of the expression of the polypeptide is probably involved in the development of these gastric cancers. Iwase et al. do not specifically discuss antibodies to the polypeptide, however it is well appreciated by one of ordinary skill in the art that such antibodies would be useful for diagnosis of gastric cancers as taught by Iwase et al. U.S. Patent No: 4816567 teaches that in the art of antibody production, monoclonal antibodies are generally preferred to polyclonal antibodies (col 2, line 17), while CDR grafted and otherwise chimeric antibodies are more preferred, see col 2, lines 40-65 and cols 15 D.6 and D.7).

Therefore, it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to make monoclonal antibodies, CDR grafted and otherwise chimeric antibodies to the polypeptide taught by Iwase et al. The desire for diagnosis of gastric cancers, being self evident from the teachings of Iwase et al., while the motivation to make monoclonal, CDR grafted, or otherwise chimeric antibodies is provided by U.S. Patent No: 4816567 wherein it is indicated that in the art of antibody production, monoclonal antibodies are generally preferred to polyclonal antibodies (col 2, line 17), while CDR grafted and otherwise chimeric antibodies are more preferred, see col 2, lines 40-65 and cols 15 D.6 and D.7).

Applicant's arguments regarding antibodies to portions of SEQ ID NO: 11 have been addressed above and are not persuasive. The skilled artisan would expect that the production of antibodies against H1 would necessarily involve portions of H1 identical to portions of SEQ ID NO: 11.

Conclusion

11. No claims are allowable.

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Brannock, Ph.D., whose telephone number is (703) 306-5876. The examiner can normally be reached on Mondays through Thursdays from 8:00 a.m. to 5:30 p.m. The examiner can also normally be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

MB

November 12, 2002

YVONNE EYLER, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600